

**Focus Report**  
New Chemicals Program  
Case Number: L-19-0033

AM

**Focus Date:** 12/20/2018

**Report Status:** Complete

**Focus Chair:** Jeff Bauer

**Contractor:** [REDACTED]

**Consolidated Set:**

**I. Notice Information**

**Submitter:** [REDACTED]

**CAS Number:** None

**Chemical Name:** [REDACTED]

**Use: Intended use:** [REDACTED]  
[REDACTED]

**Patents (same use):** None.

**Other Uses: Analogues (other uses):** [REDACTED]  
[REDACTED]

**Analogues (same + other uses):** None.

**Patents (other use):** None.

**Bind:** ☒

**imports:** ☒

**Manufacture:** ☐

**PV-max(kg/yr):** [REDACTED]

**II. SAT Results**

**Health Rating 1:** 2

**Health Rating 2:**

**Occupational Rating:** 2-3C

**Non Occupational Rating:** 2

**Ecotox Rating 2:** 3

**Environmental Rating:** 1

**Health Rating Comment 1:**

**Health Rating Comment 2:**

**Persistence 1:** 1

**Bioaccumulation 1:** 1

**Toxicity 1:**

**PBT Comments 1:** PMN

**Persistence 2:** 3

**Bioaccumulation 2:** \*

**Toxicity 2:**

**PBT Comments 2:** Deg Pdt [REDACTED], B\*(high)

**III. OTHER FACTORS**

**Categories**

**Health Chemical Category:**

**Ecotox SARs:** Carbamate Esters

**Ecotox SAR Class:** carbamate esters-perfluoro [REDACTED]

**Ecotox TSCA New Chemical Category:** None

**Related Cases / Regulatory History**

**Health Related Cases** [REDACTED] (SAME)

**Ecotox Related Cases:** Same As: [REDACTED]

**Regulatory History:** [REDACTED]  
[REDACTED]

**MSDS/Label Information**

**MSDS:** Y

**Label:** Y

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Exposure Based Information**

**Exposure Based Review (Chemistry):** N

**Exposure Based Review (Health):**

**Exposure Based Review (Ecotox):** N

**Exposure Based Review (Occupational):**

**Exposure Based Review (Non-Occupational):**

**Exposure Based Review (Environmental):**

#### **IV. Summary of SAT Assessment**

**Fate**

**Fate Summary:** L-19-0033

**FATE:**

Solid with MP = 71-73 °C (M)

S < 0.001 mg/L at 25 °C (E)

VP < 1.0E-6 torr at 25 °C (E)

BP = Dec. > 200 °C (M)

H < 1.00E-8 (E)

POTW removal (%) = 90 via sorption and biodeg; Deg Pdt [REDACTED] 0

Time for complete ultimate aerobic biodeg = PMN > mo; Deg Pdt [REDACTED] > mo

Sorption to soils/sediments = PMN strong; Deg Pdt [REDACTED] low

PBT Potential: PMN P1B1; Deg Pdt [REDACTED] P3B\*(high)

FATE: Migration to ground water = PMN slow; Deg Pdt [REDACTED] rapid

Bioconcentration factor to be put into E-FAST: Deg Pdt [REDACTED] 93

**PMN Material:**

Overall wastewater treatment removal is 90% via sorption and biodegradation.

Sorption to sludge is strong based on data for fluorinated chemicals.  
 Air Stripping (Volatilization to air) is low based on data for fluorinated chemicals.  
 Removal by biodegradation in wastewater treatment is high based on data for fluorinated chemicals.  
 Destruction of the substance in wastewater treatment is partial based on data for fluorinated chemicals.  
 The aerobic primary aquatic biodegradation half-life is less than two months based on data for fluorinated chemicals. Primary degradation of the alkyl chain and the amide is expected.  
 The aerobic ultimate aquatic biodegradation half-life is greater than six months based on data for fluorinated chemicals.  
 The anaerobic primary aquatic biodegradation half-life is two to six months based on data for fluorinated chemicals.  
 The anaerobic ultimate aquatic biodegradation half-life is greater than six months based on the aerobic biodegradation half-life. The anaerobic biodegradation half-life is projected to be greater than or equal to the aerobic biodegradation half-life.  
 Sorption to soil and sediment is strong based on data for fluorinated chemicals.  
 Migration to groundwater is slow based on data for fluorinated chemicals.  
 PMN Material:  
 Not Persistent (P1) based on the estimated aerobic primary biodegradation half-life.  
 Low Bioaccumulation (B1) based on data for fluorinated chemicals.  
 Degradation Product [REDACTED]:  
 Overall wastewater treatment removal is 0% based on low biodegradability, low sorption and low stripping.  
 Sorption to sludge is low based on data for fluorinated chemicals.  
 Air Stripping (Volatilization to air) is low based on data for fluorinated chemicals.  
 Removal by biodegradation in wastewater treatment is negligible based on data for fluorinated chemicals.  
 The aerobic aquatic biodegradation half-life is greater than six months based on data for fluorinated chemicals.  
 The anaerobic aquatic biodegradation half-life is greater than six months based on the aerobic biodegradation half-life. The anaerobic biodegradation half-life is projected to be greater than or equal to the aerobic biodegradation half-life.  
 Sorption to soil and sediment is low based on data for fluorinated chemicals.  
 Migration to groundwater is rapid based on data for fluorinated chemicals.  
 Degradation Product [REDACTED]:  
 Very Persistent (P3) based on the estimated aerobic and anaerobic biodegradation half-lives.  
 Bioaccumulation (B\*-high) based on data for fluorinated chemicals.  
 Bioconcentration/Bioaccumulation factor to be put into E-Fast: 93.

## Ecotox

### Ecotox Values

**Fish 96-h LC50:** 2.3(P)

**Daphnid 48-h LC50:** 8.3(P)

**Green Algae 96-h EC50:** 3.8(P)

**Fish Chronic Value:** 0.023(P)

**Daphnid Chronic Value:** 3.1(P)

**Green Algae Chronic Value:** 1.7(P)

**Ecotox Value Comments:** Predictions are based on QSARs for carbamate esters (ECOSAR V2.0); MW [REDACTED] Log Kow = 13.35 (P); [REDACTED] with a MP = 71-73C (M); S = 2.6E-10 mg/L (P); effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150 mg/L as CaCO<sub>3</sub>; and TOC <2.0 mg/L.

### Ecotox Factors

<b>Acute Aquatic Factors:</b>	<b>Most Sensitive Endpoint:</b> 2300	<b>Assessment Factor:</b> 5	<b>CoC:</b> 460
<b>Chronic Aquatic Factors:</b>	<b>Most Sensitive Endpoint:</b> 23	<b>Assessment Factor:</b> 10	<b>CoC:</b> 2.3

**Comments:** Environmental Hazard: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA determined environmental hazard for this new chemical substance based on an analogous chemical of the degradation product [REDACTED]. Acute toxicity values estimated for fish, aquatic invertebrates, and algae are 2.3 mg/L, 8.3 mg/L, and 3.8 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 0.023 mg/L (acute to chronic ratio (ACR)), 3.1 mg/L, and 1.7 mg/L, respectively. These toxicity values indicate that the new chemical substance is expected to have high environmental hazard. Application of assessment factors of 4 and 10

to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 0.46 mg/L (460 ppb) and 0.0023 mg/L (2.3 ppb), respectively.

Environmental Risk: Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks to the environment were not identified due to releases to water that did not exceed the acute COC or the chronic COC.

## V. Summary of Exposure/Releases

### Engineering Summary Release

Exposures/Releases	Release	Release	
Scenario	PROC: [REDACTED] Disposal	USE 1: [REDACTED]	USE 1: [REDACTED]
Site	[REDACTED]	[REDACTED]	[REDACTED]
Media	Landfill	Air	Landfill
Descriptor A	Output 2	Output 2	Output 2
Quantity A (Release=kg/site/day; Exposure=mg/day)	[REDACTED]	[REDACTED]	[REDACTED]
Frequency A (day/year)	[REDACTED]	[REDACTED]	[REDACTED]
Descriptor B			
Quantity B (Release=kg/site/day; Exposure=mg/day)			
Frequency B (day/year)			
From	[REDACTED]	[REDACTED]	[REDACTED]
Workers			
Exposure Type			

Exposures/Releases	Release	Release	
Scenario	USE 1: [REDACTED]	USE 1: [REDACTED]	USE 1: [REDACTED] (PV)
Site	[REDACTED]	[REDACTED]	[REDACTED]
Media	Landfill	Water or Air	Inhalation
Descriptor A	Output 2	Output 2	Worst Case
Quantity A (Release=kg/site/day; Exposure=mg/day)	[REDACTED]	[REDACTED]	[REDACTED]
Frequency A (day/year)	[REDACTED]	[REDACTED]	[REDACTED]
Descriptor B			Typical
			[REDACTED]

Exposures/Releases	Release	Release	
Quantity B (Release=kg/site/day; Exposure=mg/day)			
Frequency B (day/year)			
From			
Workers			
ExposureType			Vapor

Exposures/Releases	Exposure	Release	
Scenario	USE 1:	USE 2:	USE 2: Recr
Site			
Media	Inhalation	Air	Landfill
Descriptor A	Inhalable	Output 2	Output 2
Quantity A (Release=kg/site/day; Exposure=mg/day)			
Frequency A (day/year)			
Descriptor B	Respirable		
Quantity B (Release=kg/site/day; Exposure=mg/day)			
Frequency B (day/year)			
From	Worker Exposure to Particulates During Application		
Workers			
ExposureType	Particulate		

Exposures/Releases	Release	Release	
Scenario	USE 2:	USE 2:	USE
Site			
Media	Landfill	Water or Air	Inhal
Descriptor A	Output 2	Output 2	Wors Case
Quantity A (Release=kg/site/day; Exposure=mg/day)			

Exposures/Releases	Release	Release	
Frequency A (day/year)			
Descriptor B			Typic
Quantity B (Release=kg/site/day; Exposure=mg/day)			
Frequency B (day/year)			
From			
Workers			
ExposureType			Vapo

Exposures/Releases	Exposure	Release	
Scenario	USE 2: [REDACTED]	USE 3: [REDACTED]	USE 3: [REDACTED]
Site	[REDACTED]	[REDACTED]	[REDACTED]
Media	Inhalation	Water or Air or Landfill	Landfill
Descriptor A	Inhalable Particulate	Output 2	High End
Quantity A (Release=kg/site/day; Exposure=mg/day)	[REDACTED]	[REDACTED]	[REDACTED]
Frequency A (day/year)	[REDACTED]	[REDACTED]	[REDACTED]
Descriptor B	Respirable Particulate		
Quantity B (Release=kg/site/day; Exposure=mg/day)	[REDACTED]		
Frequency B (day/year)	[REDACTED]		
From	Worker Exposure to Particulates During Application	[REDACTED]	[REDACTED]
Workers	[REDACTED]		
ExposureType	Particulate		

Exposures/Releases	Exposure	Expo
Scenario	USE 3: [REDACTED]	USE 3: [REDACTED]
Site	[REDACTED]	[REDACTED]
Media	Dermal	Inhalation
Descriptor A	High End	Spray Mist

Exposures/Releases	Exposure	Expo
Quantity A (Release=kg/site/day; Exposure=mg/day)		
Frequency A (day/year)		
Descriptor B		
Quantity B (Release=kg/site/day; Exposure=mg/day)		
Frequency B (day/year)		
From		
Workers		
ExposureType	Liquid	Mist

#### Exposure Summary Release

Chemical ID: L-19-0033

Reviewer:

Exposure Scenario	Water						Land fill (non-sludge)	Stack	
Release Activity(ies) exposure Calculations	Drinking Water		Fish Ingestion						
	ADR mg/kg/day	LADD mg/kg/day	ADR mg/kg/day	LADD mg/kg/day	7Q10cc ug/l	PDM Exceeded # Days	LADD mg/kg/day	ADR mg/kg/day	LAD mg/kg/
USE1:Max ADR	2.15e-6 2.15e-6	0.00e+0	3.21e-6	0.00e+0	1.00e-1	0.00e+0	0.00e+0	0.00e+0	
USE1:PDM	0.00e+0	0.00e+0	0.00e+0	0.00e+0	1.00e-1	0.00e+0	0.00e+0	0.00e+0	
USE1:Max LADD	0.00e+0	6.56e-9	0.00e+0	4.40e-9	0.00e+0	0.00e+0	2.05e-6	0.00e+0	
USE2:Max ADR	3.12e-5 3.12e-5	0.00e+0	4.67e-5	0.00e+0	1.51e+0	0.00e+0	0.00e+0	0.00e+0	
USE2:Max LADD	0.00e+0	6.51e-9	0.00e+0	4.37e-9	0.00e+0	0.00e+0	1.91e-6	0.00e+0	
USE3:Max ADR	5.66e-4 5.66e-4	0.00e+0	8.47e-4	0.00e+0	2.74e+1	0.00e+0	0.00e+0	0.00e+0	
USE3:Max LADD	0.00e+0	1.97e-7	0.00e+0	1.32e-7	0.00e+0	0.00e+0	6.23e-8	0.00e+0	

1.Exposure scenario titles consist of release activity followed by exposure calculation abbreviation.

2.Release activities are from engineering report's Manufacturing (Mfg), Processing (Proc) and Use release activity labels. combined in one exposure scenario if their releases occur at same location.

3.Exposure calculations are Acute Dose Rate (ADR), Lifetime Average Daily Dose (LADD), and Probabilistic Dilution M one, two, or all three exposure calculations per exposure scenario. CC is the aquatic concentration of concern.

4.This column displays concentration values for the 7Q10 streamflow, which is defined as the average daily streamflow of lowest flow within a ten year period.

Result Table : Exposure Based(XB)/Persistent (P2B2) Criteria

Parameter	Exp Based	Persistent
Drinking(Surface) Water Dose (mg/kg/day)		

Parameter	Exp Based	Persistent
Fish Ingestion Dose (mg/kg/day)		
Inhalation Dose (mg/kg/day)		
Groundwater Dose (mg/kg/day)		
Surface Water Release After Treatment (kg/yr)		
Total Release After Treatment (kg/yr)		
Consumer Use?		

## VI. Focus Decision and Rationale

### Regulatory Actions

**Regulatory Decision:** LVE Conditional Denial

**Decision Date:** 12/20/2018

### Decision Type:

**Rationale:** L-19-0033 was conditionally denied based on risks to workers, the general population, consumers, and PBT concerns. This chemical substance has a PBT rating of a high P3B\*T2. The submitter should consider addressing fugitive and stack air releases, updating the SDS to include appropriate PPE (i.e., a NIOSH-certified respirator with an APF of 1,000). There is concern for lung effects based on analogy to chemicals with waterproofing properties. There is also concern for systemic and male reproductive toxicity based on acidic degradation to [REDACTED] in the stomach or in the environment.

**Workers:** Risks were not identified for workers via dermal (MOE = 23,529; benchmark MOE=23,000) exposure for systemic and male reproductive toxicity based on analogue data. Risks were identified for workers via inhalation for lung waterproofing based on structural alerts (MOE = 2.5, benchmark MOE=1000, Fold Factor = 408). Risks were identified for workers via inhalation exposure for systemic and male reproductive toxicity based on analogue data. (MOE=364; benchmark MOE=23,000, Fold Factor = 63). Risks would be mitigated if exposures can be controlled by the use of appropriate PPE, including a respirator of APF = 1000.

**General Population:** Risks were identified for general population via stack and fugitive air inhalation for lung waterproofing based on structural alerts (MOE = 2.5stack, MOE=568fugitive, benchmark MOE=1000). Risks were identified for the general population via stack air inhalation for systemic and male reproductive toxicity based on analogue data (MOE=5319; benchmark MOE=23,000). Risks were not identified for the general population via drinking water, fish ingestion, or fugitive air inhalation (MOEs => 74,940; benchmark MOE=23,000) for systemic and male reproductive toxicity based on analogue data. **Consumers:** Risks were identified for consumers via inhalation (MOE = 3.1; benchmark MOE=23,000) exposure for lung waterproofing based on structural alerts. Risks were not identified for consumers via dermal exposure (MOEdermal = 7,246,377; benchmark MOE = 100) for systemic and male reproductive toxicity. Risks were identified for consumers via inhalation exposure (MOEinhalation = 1307; benchmark MOE=23,000) for systemic and male reproductive toxicity.

**Assumptions and Uncertainties:** Absorption of the LVE is based on pchem. Metabolism is assumed to be important and is expected to degrade to [REDACTED] during digestion. There are no measured data on the LVE substance itself. Health effects are based on analogue data. The evaluation of the LVE is based on presumed metabolite/degradant.

**Ecotoxicity hazard** is estimated to be high based on QSAR predictions for carbamate esters (ECOSAR V2.0). Risks to the environment were not identified due to releases to water that did not exceed the acute COC or the chronic COC. This LVE is import only, was bound and assessed at [REDACTED] kg/yr.

COC: Acute: 460 µg/L, Chronic: 2.3 µg/L

### Summary of Exposures and Releases

Proc

[REDACTED], [REDACTED] days/yr, [REDACTED] workers

Inhalation: Negligible (VP < 0.001 torr)

Dermal: Not expected

Releases via Landfill: [REDACTED]

Fate Releases to Air

Stacked Air: LADD: 1.25E-05 mg/kg/day



#### Use1

■ sites, ■ days/yr, ■ workers  
Inhalation (Vapor): Typical: ■ mg/day, Worst Case: ■ mg/day  
Inhalation (Particulate): Respirable: ■ mg/day, Total: ■ mg/day  
Dermal: Not expected

Releases to Water: ■

Or Air

Releases to Air: ■

Releases via Incineration: ■

Or Landfill

Releases via Incineration: ■

Or Landfill

#### Fate Releases to Water (0% Removal)

SWC: 3.96E-02 µg/L

DW: LADD: 6.38E-09 mg/kg/day, ADR: 8.20E-07 mg/kg/day

FI: LADD: 4.28E-09 mg/kg/day, ADR: 1.23E-06 mg/kg/day

#### Fate Releases to Air

Stacked Air: LADD: 1.34E-06 mg/kg/day, ADR: 5.16E-05 mg/kg/day

Fugitive Air: LADD: 1.48E-08 mg/kg/day, ADR: 1.43E-06 mg/kg/day

#### Fate Releases via Landfill

LADD: 1.94E-06 mg/kg/day

#### Use2

■ sites, ■ days/yr, ■ workers  
Inhalation (Vapor): Typical: ■ mg/day, Worst Case: ■ mg/day  
Inhalation (Particulate): Respirable: ■ mg/day, Total: ■ mg/day  
Dermal: Not expected

Releases to Water: ■

Or Air

Releases to Air: ■

Releases via Incineration: ■

Or Landfill

Releases via Incineration: ■

Or Landfill

#### Fate Releases to Water (0% Removal)

SWC: 1.51 µg/L

DW: LADD: 6.51E-09 mg/kg/day, ADR: 3.12E-05 mg/kg/day

FI: LADD: 4.37E-09 mg/kg/day, ADR: 4.67E-05 mg/kg/day

#### Fate Releases to Air

Stacked Air: LADD: 1.31E-06 mg/kg/day, ADR: 1.88E-03 mg/kg/day

Fugitive Air: LADD: 1.11E-08 mg/kg/day, ADR: 4.01E-05 mg/kg/day

#### Fate Releases via Landfill

LADD: 1.91E-06 mg/kg/day

#### Use3

■ sites, ■ days/yr, ■ workers  
Inhalation (Mist): Typical: ■ mg/day, Worst Case: ■ mg/day  
Dermal: ■ mg/day (1.50% Liquid)

Releases to Water: ■

Or Air or Incineration or Landfill

Releases to Water: ■

Or Incineration or Landfill

Fate Releases to Water (0% Removal)

SWC: 1.55 µg/L

DW: LADD: 6.67E-09 mg/kg/day, ADR: 3.20E-05 mg/kg/day

FI: LADD: 4.48E-09 mg/kg/day, ADR: 4.79E-05 mg/kg/day

Fate Releases to Air

Stacked Air: LADD: 4.20E-08 mg/kg/day, ADR: 2.01E-06 mg/kg/day

Fugitive Air: LADD: 3.38E-07 mg/kg/day, ADR: 3.26E-05 mg/kg/day

PDM

Fate Releases to Water (0% Removal)

SWC: 1.23 µg/L

DW: LADD: 1.99E-07 mg/kg/day, ADR: 2.54E-05 mg/kg/day

FI: LADD: 1.34E-07 mg/kg/day, ADR: 3.80E-05 mg/kg/day

Fate Releases via Landfill

LADD: 6.23E-08 mg/kg/day

CEM, User Defined

Inhalation: LADD: 4.59e-05 mg/kg/day, ADR: 7.65e-03 mg/kg/day

Dermal: LADD: 8.31e-06 mg/kg/day, ADR: 1.38e-03 mg/kg/day

CEM, User Defined

Inhalation: LADD: 3.67e-04 mg/kg/day, ADR: 7.65e-03 mg/kg/day

Dermal: LADD: 6.65e-05 mg/kg/day, ADR: 1.38e-03 mg/kg/day

**P2 Rec Comments:**

**Testing**

**Health:**

**Ecotox:**

**Fate:**

**Final Recommendations**